PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
A0619/7001WO		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 95/ 11160	01/09/1995	02/09/1994
International Patent Classification (IPC) or national classification and IPC		
A61K39/02		
Applicant		
BRIGHAM AND WOMEN'S HOSPITAL, INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consists of a total of 9 sheets.

3. This report contains indications and corresponding pages relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☒ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
02/04/1996	21.11.96
Name and mailing address of the IPEA/	Authorized officer
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Intern. application No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT PCT/US95/11160

I. Basis of the report

1. This report has been drawn up on the basis of (Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.):

[ ] the international application as originally filed.

[x] the description, pages 1,3,5,6,8-18,21-30_____, as originally filed,
pages _____, filed with the demand,
pages 2,4,7,19,20_____, filed with the letter of 06.05.96,
pages _____, filed with the letter of _____,

[x] the claims, Nos. _____, as originally filed,
Nos. _____, as amended under Article 19,
Nos. _____, filed with the demand,
Nos. 1-29_____, filed with the letter of 30.10.96,
Nos. _____, filed with the letter of _____,

[ ] the drawings, sheets/fig _____, as originally filed,
sheets/fig _____, filed with the demand,
sheets/fig _____, filed with the letter of _____,
sheets/fig _____, filed with the letter of _____.

2. The amendments have resulted in the cancellation of:
[ ] the description, pages _____.
[ ] the claims, Nos. _____.
[ ] the drawings, sheets/fig _____.

3. [ ] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

known from the cited prior art documents cited in the Search Report, but none of the latter discloses their use for the protection against abscess formation. Except for the document "Clinical infectious Diseases 20 (supp. 2) 1995, S132 to S140" (referred to hereafter as D1), said documents mainly describe the effect of CPC and its components on the induction of abscesses and not as a "medicament" or "pharmaceutical" for protecting against said abscesses. With respect to D1, the Applicant submitted a joint declaration of the inventors, that the data in D1 which discloses that one purified molecule of CPC can cross-protect against abscess formation when the animal is challenged with another different molecule was not presented by the inventors at the cited meeting in 1994, thus was not available to the public before the priority date of the present application.

In this context it is noted that the prior art abscess protection assays conducted with isolated CPC complexes are not considered to be comparable to assays with single components of such complexes. Furthermore prior art protection assays involving isolated CPC of B. fragilis did not show that CPC could protect against abscess formation by strains other that the strain used for inducing the abscess.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims 1-29	YES
	Claims	NO
Inventive Step (IS)	Claims 1-29	YES
	Claims	NO
Industrial Applicability (IA)	Claims 1-29	YES
	Claims	NO

2. CITATIONS AND EXPLANATIONS

The subject-matter of method claims 1-10 appears to satisfy the requirements of Article 33(2) and (3) PCT, as none of the prior art documents cited in the International Search Report discloses or suggests a method for inducing protection against abscess formation caused by infection by live heterologous microorganisms comprising the administration of a polymer or polysaccharide formed of a plurality of a repeating unit, whereby each such unit has a charge motif characteristic of polysaccharide A as defined in claim 1, and the polymer or polysaccharide being free from complexation as part of B. fragilis capsular polysaccharide complex.
(With respect to claims 1 and 6 (insofar as the latter refers back to claim 1) which only mention a polymer without restriction to a polysaccharide, please see section VIII of the present report).

In this context it should be noted that for the assessment of the above-mentioned claims 1-10 on the question whether they are industrially applicable, no unified

criteria exist in the PCT. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but will allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

The subject-matter of the remaining claims 11-29 which relates to a pharmaceutical containing said polymer or polysaccharide or to a method for producing the same, as well as to the polymer or polysaccharide per se for a "first medical use" or a "second medical use" is also considered to be novel and to involve an inventive step. It should be noted that as the PCT does not provide regulations specifically concerning "first" and "second" medical use claims, the interpretation of the subject-matter of the claims in question with respect to novelty and inventive step is therefore that which is followed in the EPC.

None of the available prior art documents discloses the induction of protection against abscess formation by other (antigenically distinct) strains of B. fragilis or even distinct species of microorganisms, by a single component of the CPC complex of a single strain of B. fragilis. In the present application it has been shown that various polysaccharides may induce protection against abscess formation as long as each of their repeating units presents the charge motif characteristic of polysaccharide A, i.e. one positively charged free amino moiety and a negatively charged moiety selected from the group consisting of carboxyl, phosphate, phosponate, sulfate and sulfonate.

Such polysaccharides (e.g. PSA) are per se indeed well

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)

In case the priority date of the present application was not valid, then the document "Infect. Immun. (1994), 62(11), 4881-6, November 1994 would become relevant in the context of novelty and inventive step.

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

The document D1 has not been identified in the description nor has the relevant background art disclosed therein been discussed. The requirements of Rule 5.1(a)(ii) PCT are, thus, not fulfilled.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. In claims 1,11,16,18,25 and 27 the polymers used for the protection against abscess formation are not limited to polysaccharides. Such an embodiment does not appear to be supported by the description or any of the examples (Article 6 PCT). In this respect, it is also not clear whether the description is enabling for the use of polymers other than polysaccharides, or in other words sufficiently clear and complete for the invention (when relating to the use of polymers other than polysaccharides) to be carried out by a person skilled in the art (Article 5 PCT).

2. With respect to the remaining claims which do specifically mention polysaccharides, it is considered that the scope of said claims also appears to be broad, but as none of the documents cited in the Search Report may be cited in the context of Articles 33(2) or (3) PCT in this respect and as the description and examples support the use of polysaccharides, no objection under Article 6 PCT is raised.
In this respect any references to unmodified "naturally occuring bacterial polysaccharides" for use in a "first medical use" in the description do not satisfy the requirements of Article 6 PCT as they render the scope of the claims unclear. For instance the last phrase of the last paragraph at page 4, implies that naturally occuring bacterial polysaccharides that have previously may have been used as immunogens to stimulate a humoral b cell response (thus a "first medical use") may used as products of the invention. The same objection is valid for the general statement at page 11, second paragraph, first phrase and at page 30, last paragraph.